

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

UNITED STATES OF AMERICA
ex rel. MARGARET BROWN,

Plaintiff and Relator,

v.

LABORATORY CORPORATION OF
AMERICA HOLDINGS

and

TRI-STATE CLINICAL
LABORATORY SERVICES, LLC,

Defendants.

Civil Action No. 1:09-cv-00871

Judge Spiegel

FILED UNDER SEAL
Pursuant to 31 U.S.C. § 3730(b)(2)
and Local Rule 3.2

DO NOT SERVE

COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT

I. INTRODUCTION.

1. *Qui Tam* Relator Margaret Brown bring this action on her own behalf and on behalf of the United States of America to recover damages and penalties under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, against Defendants Laboratory Corporation of America Holdings and Tri-State Clinical Laboratory Services, LLC. The violations arise out of Defendants' actions to cause the submission of false claims for payment to Medicaid, Medicare, TRICARE, and other federally-funded government healthcare programs for laboratory services performed as a result of illegal financial relationships between Defendants and their referral sources.

2. This complaint details the fraudulent conduct of Defendants to secure the use of its services products through illegal referral schemes with health entities in a

position to refer patients, including through improper investment and ownership relationships and the improper provision of free equipment and other services.

II. JURISDICTION AND VENUE.

3. This action arises under the United States Civil False Claims Act, 31 U.S.C. § 3729 *et seq.*

4. The Court has subject-matter jurisdiction pursuant to 31 U.S.C. § 3732 (a) and 28 U.S.C. § 1331, and has personal jurisdiction over the Defendants because the defendants do business and are located in this district.

5. Venue lies under 28 U.S.C. 1391 (b), (c) and 31 U.S.C. 3732 (a) because Defendants operate and transact business within this district.

6. The allegations of this complaint have not been publicly disclosed in a criminal, civil, or administrative hearing, nor in any congressional, administrative, or General Accounting Office report, hearing, audit, or investigation, nor in the news media.

7. Relator is an original source of the information upon which this complaint is based, as that phrase is used in the False Claims Act and other laws at issue herein.

8. Relator provided disclosure of the allegations of this complaint to the United States prior to filing.

III. **PARTIES.**

10. The real party in interest to the claims set forth herein is the United States of America.

11. The United States of America is the real party in interest

12. The Relator, Margaret Brown, is a resident of Kentucky. She has more than ten years experience managing clinical laboratories. Ms. Brown received her undergraduate degree in Clinical Laboratory Science from Eastern Kentucky University in 1996. Ms. Brown was hired by Tri-State Clinical Labs in November 2008 to be the Manager of the Clinical Laboratory as well as the Quality and Compliance Manager. Ms. Brown was terminated by Tri-State Labs on June 2, 2009.

13. Defendant Tri-State Clinical Laboratory Services, LLC ("Tri-State Labs") is a full-service medical testing laboratory located at 1737 Tennessee Avenue, Cincinnati, Ohio 45229. Tri-State Labs began operations in January 2009 and is a joint venture between Defendant LabCorp and Greater Cincinnati Pathologists, a Cincinnati-based medical practice group. Tri-State Labs provides medical testing services to provider customers, including several Cincinnati-area hospitals, including clinical testing as well as anatomic pathology, microbiology, and cytology services.

14. Defendant Laboratory Corporation of America Holdings ("LabCorp") is a publicly traded corporation (NYSE: LH) headquartered in Burlington, North Carolina. According to its website, "LabCorp provides leading-edge medical laboratory tests and services through a national network of primary clinical laboratories and specialized Centers of Excellence." LabCorp employs roughly 28,000 persons worldwide, and

performs in excess of one million individual tests each day on some 400,000 specimens.

15. Defendants Tri-State Labs and LabCorp shall be collectively referred to herein as Defendants or Tri-State Labs.

IV. RULE 9(b), FED. R. CIV. P. ALLEGATIONS.

16. Much of the documentary evidence necessary to prove the allegations in this Complaint is in the exclusive possession of either the defendant or the United States.

17. With respect to each allegation herein made upon information and belief, Relator has, based upon her knowledge, data, and experience, a reasoned factual basis to make the allegation but lacks complete details of it.

18. Relator is familiar with Tri-State Labs internal structure, policies, and procedures as a result of her employment relationship with Defendants and personally observed the practices alleged herein.

19. However, Relator does not have access to all of the information regarding the claims for payment submitted or caused to be submitted by Defendants. This information is in Defendants' exclusive possession and control.

20. Defendants have submitted and caused to be submitted and, upon information and belief, continues to submit or causes to be submitted to the United States false claims for payment for noncovered and nonpayable laboratory testing which were performed as a result of an illegal financial relationships in violation of the Stark and Anti-kickback laws.

21. Upon information and belief, Relator alleges that Defendants' fraudulent scheme has occurred continuously since the establishment of Tri-State Labs.

V. THE STATUTORY AND REGULATORY ENVIRONMENT.

A. THE STARK LAWS.

22. Enacted as amendments to the Social Security Act, 42 U.S.C. § 1395nn (commonly known as the "Stark Statute") prohibits an entity providing healthcare items or services from submitting Medicare claims for payment based on patient referrals from physicians having a "financial relationship" (as defined in the statute) with the hospital. The regulations implementing 42 U.S.C. § 1395nn expressly require that any entity collecting payment for a healthcare service "performed under a prohibited referral must refund all collected amounts on a timely basis." 42 C.F.R. § 411.353.

23. A financial relationship under the Stark laws specifically includes a relationship where the physician has an ownership or investment interest in an entity. 42 U.S.C. § 1395nn(a)(2)(A).

24. Congress enacted the Stark Statute in two parts, commonly known as Stark I and Stark II. Enacted in 1989, Stark I applied to referrals of Medicare patients for clinical laboratory services made on or after January 1, 1992 by physicians with a prohibited financial relationship with the clinical lab provider. Omnibus Budget Reconciliation Act of 1989, P.L. 101-239, § 6204.

25. In 1993, Congress extended the Stark Statute (Stark II) to referrals for ten additional designated health services (DHS) effective January 1, 1995, including (1) inpatient and outpatient hospital services; (2) physical therapy; (3) occupational therapy; (4) radiology; (5) radiation therapy (services and supplies); (6) durable medical

equipment and supplies; (7) parenteral and enteral nutrients, equipment, and supplies; (8) prosthetics, orthotics, and prosthetic devices and supplies; (9) outpatient prescription drugs; and (10) home health services. 42 U.S.C. § 1395nn(h)(6).

26. Both the professional and technical components of the laboratory services which are the subject of this complaint are a designated health service (DHS) under Stark laws.

27. The Stark statute provides:

(a) Prohibition of certain referrals

(1) In general

Except as provided in subsection (b) of this section, if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then --

(A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and

(B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

42 U.S.C. § 1395nn (emphasis added).

28. The Stark Statute defines "referral" as "the request or establishment of a plan of care by a physician which includes the provision of designated health services." 42 U.S.C. § 1395nn(h)(5)(A). Federal regulations implementing the statute also define "referral" as, among other things, "a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare...." 42 C.F.R § 411.351. A referring physician is defined as "a physician who makes a referral

as defined in this section or who directs another person or entity to make a referral or who controls referrals made to another person or entity." *Id.*

29. The Stark laws expressly prohibits any entity from presenting or causing the presenting of any claim resulting from a referral from a physician who has a financial relationship with the entity, which includes ownership interests, unless that relationship fits into one of the specific exceptions in the statute. For example, certain ownership interests in publicly-traded securities and in hospital entities are excepted. See 42 U.S.C. § 1395nn(d). Such exceptions are not applicable to the allegations in this case.

B. ANTI-KICKBACK ACT.

30. Pursuant to the Anti-Kickback Act, 42 U.S.C. Section 1320a-7b(b), it is unlawful to knowingly offer or pay any remuneration in cash or in kind in exchange for referring, recommending or arranging for federally-funded medical services, including services provided under the Medicare, Medicaid and (as of January 1, 1997) TRICARE programs. In pertinent part, the statute states:

(b) Illegal remuneration

(1) whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind --

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

(2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person --

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b). Violation of the statute can also subject the perpetrator to exclusion from participation in federal health care programs and, effective August 6, 1997, civil monetary penalties of \$50,000 per violation and three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

31. The Anti-Kickback Act is designed to, *inter alia*, ensure that patient care will not be improperly influenced by inappropriate compensation from the healthcare industry.

32. Each of the federally-funded health care programs requires every provider who seeks payment from the program to promise and ensure compliance with the provisions of the Anti-Kickback Act and other federal laws governing the provision of health care services in the United States.

33. Payment of remuneration of any kind violates the statute if one or any purpose for that remuneration was to induce referrals. Moreover, payments to physicians in return for the physicians' promises to send patients to a particular facility qualify as kickbacks. Giving a person the opportunity to earn money may also constitute an inducement under the Anti-kickback statute.

C. REIMBURSEMENT BY GOVERNMENT-FUNDED HEALTH CARE PROGRAMS.

34. The Health Insurance for the Aged and Disabled Program, popularly known as the Medicare program, was created in 1965 as part of the Social Security Act (SSA). The Secretary of HHS administers the Medicare Program through CMS, a component of HHS.

35. The Medicare program consists of two parts. Medicare Part A authorizes the payment of federal funds for hospitalization and post-hospitalization care. 42 U.S.C. § 1395c-1395i-2 (1992). Medicare Part B authorizes the payment of federal funds for medical and other health services, including without limitation physician services, supplies and services incident to physician services, laboratory services, outpatient therapy, diagnostic services, and radiology services. 42 U.S.C. § 1395(k), 1395(i), 1395(s).

36. Reimbursement for Medicare claims is made by the United States through the Department of Health and Human Services (HHS). The Centers for Medicare and Medicaid Services (CMS) is an agency of HHS and is directly responsible for the administration of the Medicare Program. CMS, in turn, contracts with private insurance carriers to administer and pay claims from the Medicare Trust Fund. 42 U.S.C. §

1395u. In this capacity, the carriers act on behalf of CMS. 42 C.F.R. § 421.5(b) (1994).

These entities are called fiscal intermediaries.

37. Compliance with both the Anti-kickback Act and the Stark laws is a condition of payment from federally-funded healthcare programs.

38. Every Medicare and Medicaid provider or supplier are required to sign a Provider Agreement. Each entity or person which signs a Provider Agreement certifies:

I agree to abide by the Medicare laws, regulations and program instructions that apply to [this provider/supplier/physician]. The Medicare laws, regulations, and program instructions are available through the [Medicare contractor].

I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare.

39. Tri-State Labs rendered laboratory services for hospitals and other healthcare entities, as alleged herein. Laboratory services are generally paid for under Part B of the Medicare program, unless provided to Medicare Part A inpatients and included as part of the per diem amount on Part A claims. Laboratory services are also paid by state Medicaid agencies and by other federally-funded healthcare programs.

40. As a result of its scheme to utilize improper financial relationships to obtain referrals from healthcare entities, Tri-State Labs submitted and caused the submission of false claims to the United States in violation of Stark and Anti-Kickback Laws.

VI. ALLEGATIONS OF FACT.

41. Tri-State Labs is a joint venture between LabCorp and Greater Cincinnati Pathologists ("GCP"), a medical practice group comprised of Cincinnati pathologists.

42. Tri-State Labs was formed when three GCP members—Drs. Blake Nestok, James Devitt, and Mohammed Nazek—approached LabCorp with the idea of establishing a full-service, Cincinnati-based laboratory.

43. Tri-State Labs began operations in January 2009.

44. Tri-State Labs incorporates four laboratory areas: Clinical, Anatomical Pathology (AP), Microbiology, and Cytology. During her employment with Tri-State Labs, Relator was the manager of the Clinical area.

45. Tri-State Labs provides laboratory services to numerous Cincinnati-area hospitals and providers, including but not limited to:

- a. The Health Alliance
- b. Christ Hospital
- c. St. Luke Hospital (East)
- d. St. Luke Hospital (West)
- e. Margaret Mary Community Hospital
- f. Brown County Hospital
- g. Redbank Surgery Center
- h. Chancellor Surgery Center
- i. Jewish Hospital
- j. Drake Center
- k. Ft. Hamilton Hughes Hospital

- l. University of Cincinnati Hospital
- m. West Chester Medical Center
- n. Brown County Hospital
- o. Alliance Employee Health Center

46. Each provider determines the types of samples it will send Tri-State Labs.

For example, some providers send both Clinical and AP samples for analysis, while others only send AP samples.

A. False Claims Resulting From Improper Financial Relationships Between Tri-State Labs and its Customer Health Care Entities.

47. In addition to their joint ownership interest in Tri-State Labs, Drs. Nestok, Devitt, and Nazek also hold management positions within several of Tri-State Labs's hospital customers. These doctors have used, and continue to use, their respective positions to guarantee a continued stream of referrals to Tri-State Labs

48. Dr. Nazek is the Director of Anatomic Pathology at Christ Hospital, as well as a staff pathologist. In addition, Dr. Nazek is the President and Medical Director of Tri-State Labs.

49. Dr. Nestok is a pathologist on staff at Christ Hospital, and, upon information and belief, is the Cytology Medical Director at Christ. Dr. Nestok is also the Cytology Medical Director at Tri-State Labs.

50. Dr. Devitt is the Medical Director of the laboratory at Christ Hospital, St. Luke Hospital East and West, and Margaret Mary Community Hospital, and is affiliated with Red Bank Surgery Center. Dr. Devitt is also the Medical Director of the Anatomical Pathology and Clinical sides of Tri-State Labs.

51. Notwithstanding their financial relationship with Tri-State Labs, Drs. Nazek, Nestok, and Devitt refer laboratory services for their patients to Tri-State Labs for processing and billing to federally-funded programs. Those referrals result in the submission of claims to the United States.

52. Additionally, each of the health care entities with which Drs. Nazek, Nestok, and Devitt, as well as other members of GCP, have a financial relationship entered into referral contracts with Tri-State Labs for all the laboratory services rendered for patients treated at those entities.

53. Upon information and belief, Drs. Nazek, Nestok, and Devitt and other members of GCP are in a position to direct or control referrals at the health care entities that contract with Tri-State Labs.

54. Indeed, each of these doctors, as medical directors at these facilities, generally appear as the referring physician on each specimen's requisition form, along with the patient's attending or ordering physician.

B. False Claims Resulting from Illegal Incentives Offered and Paid For Referrals.

54. Tri-State Labs has provided and, upon information and belief, continues to provide, several of its hospital clients with illegal incentives to refer samples to Tri-State Labs. These incentives included, but were not necessarily limited to expensive laboratory equipment and supplies, as well as other financial inducements.

55. Tri-State Labs has purchased various pieces of laboratory equipment for some of its hospital clients. This equipment was provided to the hospitals free of

charge, and is used solely by the recipient hospital for its own benefit. The following chart indicates the particular equipment purchased:

Hospital Customer	Equipment	Quantity
Jewish Hospital	Cryostat	1
	Cassette Labeler	1
University Hospital	Cryostat	2
	Leica Cassette Labeler	2
Red Bank Surgery Center	Cryostat	1
	Cassette	1
West Chester Medical Center	Cryostats	2

56. This equipment was provided by Tri-State Labs to its hospital customers at below fair market value with a purpose of inducing the hospital customers to refer services to Tri-State Labs paid in whole or part by federal programs.

57. Tri-State Labs has also provided equipment maintenance services free of charge. For example, Tri-State Labs provides maintenance services on equipment owned by St. Luke Hospital East and St. Luke Hospital West. These services were provided by Tri-State Labs to its hospital customers below fair market value with a purpose of inducing the hospital customers to refer services to Tri-State Labs paid in whole or part by federal programs.

58. In addition to providing equipment and equipment maintenance services to hospital clients free of charge, Tri-State Labs has also provided its hospital clients with medical supplies. According to Tri-State Labs's master ordering checklist, the following types of items have been ordered for its clients' benefit:

- a. Aero-Med #60 Autopsy Scalpel Blade 150/Case
- b. Surgipath Blade Scalpel #60 100/Box

- c. Cardinal Health Blade Accu-Edge Autopsy Semidisp Brain Knife
5/Case
- d. Mopec Inc. Autopsy Saw Blade
- e. Mopec Inc. Knife Disposable Lung 10/Box
- f. Mopec Inc. Autopsy Saw 115V
- g. Richard Allen Bag Biopsy Tissue 30X40mm

59. Upon information and belief, these supplies were provided to one or more hospital clients at below fair market value with a purpose of inducing them to refer services to Tri-State Labs.

60. The provision of these below market value incentives, to include free equipment, maintenance and supplies, creates an improper financial relationship in violation of the Stark and Anti-Kickback laws.

61. Tri-State Labs submitted or caused to be submitted false claims for laboratory services referred by these entities while engaged in these improper financial relationships.

C. Retaliatory and Wrongful Termination of Relator.

62. The Relator was hired by Tri-State Labs to serve as Lab Manager and Compliance and Quality Manager. Relator's position required her to draft compliance policies, and to ensure that lab operations were conducted according to federal and state laws and regulations, and to maintain current records relating to compliance training.

63. In the performance of her position, Relator observed many instances of improper conduct by Defendants which she brought to the attention of her supervisors and colleagues. This conduct included conduct which violated federal and state law.

64. Several examples are illustrative. On numerous occasions prior to June 2, 2009, the Relator explained to Elizabeth Long, Tri-State Labs's General Manager, that Tri-State Labs's CAP licensure paperwork was not compliant due to the fact that Dr. Devitt was listed as the Tri-State Labs's Medical Director, when in fact Dr. Nazek was the Medical Director. Additionally, Relator advised Ms. Long that Dr. Nazek, rather than Dr. Devitt, was required to sign Tri-State Labs' Standard Operating Procedures ("SOP"), Policies, and Instrument/Assay validations. Despite Relator's reports regarding the laboratory's violations, Ms. Long instructed Relator to obtain Dr. Devitt's signature. Relator later discussed the matter on March 9, 2009, with Lorelee Coe, a LabCorp compliance manager. Ms. Coe agreed that a verbal assignment of duties from Dr. Nazek to Dr. Devitt was insufficient.

65. On numerous occasions prior to June 2, 2009, Relator requested from Ms. Long the various contracts between Tri-State Labs and its provider customers and vendors. Relator explained to Ms. Long that without seeing the contracts, there was no way for Relator to know who was responsible for maintaining the equipment used in by TCL. Relator also advised Ms. Long that, as a matter of compliance, the contracts needed to be on hand and available for review by inspectors. Notwithstanding her requests, Ms. Long stated that Relator had no need for the contracts, and that LabCorp would handle them.

66. Relator questioned the nature of the relationships between the hospital referral sources and the laboratory on many occasions. For example, on March 3, 2009, Relator again requested the contracts from Ms. Long, and also voiced her concern that the relationships between Tri-State Labs and Drs. Nazek, Devitt, and Nestok could constitute violations of the Stark law. Ms. Long instructed Relator to "leave it alone" as such matters were handled by LabCorp's legal and compliance personnel. Not satisfied with this answer, Relator discussed the matter with Ms. Lorelee, again stressing that the ownership arrangement might violate the Stark law. Ms. Lorelee suggested that Relator obtain the contracts for her and the Relator to review together. Ms. Lorelee recommended that Relator request the contracts from Donna Dudley, then a Vice President with LabCorp in Columbus, Ohio. Relator did contact Ms. Dudley in order to request the contracts, but she received no response.

67. On March 10, 2009, Relator asked to speak with Mark Braune, the new CEO of Tri-State Labs, regarding Tri-State Labs's purchase of equipment and supplies for its customers. Relator expressed her concern that these purchases might constitute illegal kickbacks. Relator also expressed her concern that the ownership of TCL by pathologists who personally refer samples to TCL and who have influence of the referral of samples by provider customers might amount to violations of the Stark law. Mr. Braune responded that he would look into it, but never reported back to Relator.

68. On June 1, 2009, Tri-State Labs received a surprise inspection from the State of Ohio. According to the inspector, the inspection was based upon an anonymous complaint. The inspector toured the Tri-State Labs facilities, and asked to see validation information, standard operating procedures, policies for compliance and

quality, instrument printouts of patient results, in addition to other documents including employee credentials. The inspector issues recommendations for AP and Micro, but not for an area of Relator's responsibility. Indeed, the inspector commented on the fact that Relator's records were accurate and in order.

69. Despite her superior performance on the inspection, Relator was terminated without cause the following day, on June 2, 2009. Relator was informed that her employment was "at will," so no explanation needed to be provided. Mr. Braune additionally commented that they did not feel Relator would take Tri-State Labs in the direction desired by management.

70. Upon information and belief, Relator was terminated in retaliation for her objections to improper conduct in violation of governing laws and regulations which resulted in false claims to the United States.

COUNT I

Violations of the False Claims Act

71. The allegations in the foregoing paragraphs are realleged as if fully set forth herein.

72. The False Claims Act, 31 U.S.C. § 3729(a)(1)(A) and (B), imposes liability upon, *inter alia*, those who knowingly cause to be presented false claims for payment or approval, and those who make or use, or cause to be made or used, false records or statements material to a false claim.

73. Compliance with the Stark and Anti-Kickback laws is a condition of payment of Medicare, Medicaid and other federally-funded healthcare programs.

74. Pursuant to the Stark laws, 42 U.S.C. § 1395nn, it is unlawful for a physician to make a referral for the provision of medical services, including clinical laboratory services, to an entity in which the physician has a financial interest. Further, it is unlawful for an entity to present a claim or cause to be presented a claim for reimbursement to a third party payor, including the federal Medicare program, based upon any service rendered as a result of a referral from a physician who has a financial interest in the entity. An ownership interest constitutes a financial interest under the Stark laws

75. Additionally, it is a felony, pursuant to the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, to knowingly offer and pay any remuneration, in cash or in kind, to any person for the referral of an individual for the provision of medical services which are subsequently billed to the federal Medicare program.

76. Claims for payment to federally-financed healthcare systems, to include at least Medicaid, Medicare, and Tricare, which resulted from unlawful referrals in violation of the Stark laws and/or violation of the Anti-Kickback Statute are false claims.

77. Defendants' improper financial relationships with its hospital and other healthcare entities were in violation of Stark and Anti-Kickback laws, and resulted in false claims for payment to the United States, in violation of 31 U.S.C. §3729(a)(1)(A).

78. In the furtherance of these schemes, Defendants also caused to be made or used false records or statements material to a false claim in violation of 31 U.S.C. § 3729(a)(1)(B).

79. Defendants acted knowingly, as that term is used in the False Claims Act.

80. Because the United States would not have paid for services which it knew to have been the result of illegal self-referral and kickback schemes, the United States has been harmed in an amount equal to the value paid by the United States.

81. The United States Government has been damaged as a result of Defendant's conduct in violation of the False Claims Act in an amount to be determined at trial.

COUNT II

Retaliation in Violation of the False Claims Act, 31 U.S.C. § 3730(h)

82. The allegations in the foregoing paragraphs are re-alleged as if fully set forth herein.

83. From approximately January 4, 2009 through June 2, 2009, Relator engaged in lawful acts done in furtherance of other efforts to stop one or more violations of 31 U.S.C. § 3729.

84. Because of Relator's lawful acts described above, Relator was subjected to discrimination in the terms and conditions of her employment by Tri-State Labs, including but not necessarily limited to her termination on June 2, 2009.

85. The Defendants' discrimination against Relator was a violation of 31 U.S.C. § 3730(h).

86. As a consequence of Defendants' violation of 31 U.S.C. § 3730(h), Relator suffered damages.

COUNT III

Retaliation and Wrongful Discharge in Violation of the Ohio Whistleblower Statute, Ohio Rev. Code Ann. § 4113.52, Public Policy, and Common Law

87. The allegations in paragraphs are realleged as if fully set forth herein.

88. During the period beginning approximately January 4, 2009 and continuing through June 2, 2009, Relator, during the course of her employment at Tri-State Labs, became aware that the Defendant was in violation of federal and state laws, including the Stark Laws and the Anti-kickback Statute.

89. Relator took steps to advise Tri-State Labs management and other personnel that Tri-State Labs was engaged in violations of the laws, including the Stark laws and Anti-Kickback Statute, including but not limited to, reporting such violations to Tri-State Labs CEO Mark Braune.

90. As a direct and proximate consequence of her efforts to advise Tri-State Labs management and other personnel of such violations, her employment at Tri-State Labs was terminated.

91. Tri-State Labs lacked an overriding legitimate business objective for terminating Relator's employment. To the contrary, Relator's termination was due to her internal reporting of Tri-State Labs' violations of federal and state law.

92. There is a clear public policy in the State of Ohio favoring the protection of whistleblowers from retaliatory acts by their employers, and manifested in Ohio Rev. Code Ann. § 4113.52. There is also a clear public policy in the State of Ohio favoring adherence to federal statutes, including the Stark law and the Anti-Kickback Statute.

93. Permitting employers such as Tri-State Labs to discharge employees such as Relator for internal reporting of violations of the federal statutes, including the Stark law and the Anti-Kickback Statute, would jeopardize these public policies.

94. Relator was retaliated against and wrongfully discharged in violation of Ohio law, as reflected by both statute and common law, including but not limited to the Ohio Whistleblower Statute, Ohio Rev. Code Ann. § 4113.52.

PRAYER FOR RELIEF

WHEREFORE, Relator requests:

A. That the Court enter judgment against the Defendants in an amount equal to three times the amount of damages the United States Government has sustained because of Defendants' actions, plus a civil penalty of \$11,000 for each action in violation of 31 U.S.C. § 3729, and the costs of this action, with interest, including the costs to the United States Government for its expenses related to this action;

B. That in the event the United States Government intervenes in this action, Relator be awarded 25% of the proceeds of the action or the settlement of any such claim;

C. That in the even the United States Government does not proceed with this action, Relator be awarded 30% of the proceeds of this action or the settlement of any such claim;

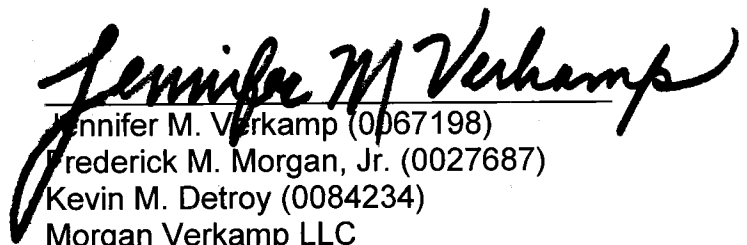
D. That Relator be awarded all costs, attorneys' fees, and litigation expenses;

E. That the Relator be awarded all damages caused by the Defendants' retaliation and wrongful termination of her, including but not limited to two times the

amount of back pay owed to him, interest on such back pay, lost benefits, compensatory and punitive damages, and prejudgment interest to which she is entitled;

- F. That Relator be awarded all costs, attorneys' fees, and litigation expenses;
- G. That the United States Government and Relator receive all relief, both at law and in equity, to which they may reasonably appear entitled.

Respectfully submitted,



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